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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,791	11/29/2001	Geert Maertens	2551-68	9146

23117 7590 12/17/2004

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EXAMINER

MOSHER, MARY

ART UNIT PAPER NUMBER

1648

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/995,791	Applicant(s) MAERTENS ET AL.	
	Examiner Mary E. Mosher, Ph.D.	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/30/04, 7/13/04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16, 17, 20-29 and 31-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16, 17, 21-28, 32, 34 and 37-39 is/are rejected.
- 7) ☒ Claim(s) 29, 31, 33, 35 and 36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/06)
Paper No(s)/Mail Date <u>4/16/02, 7/13/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

In response to the Request filed July 13, 2004, an initialed copy of the April 16, 2002 PTO-1449 is enclosed, it was prepared with the last Office action but it apparently was not scanned or mailed, perhaps because applicants provided the wrong application number on the form. The drawing approval box on the 326 form is also now marked.

Response to Amendment

In response to the amendments and arguments presented in the response filed 9/30/2004, the rejections under 112, first paragraph and 112, second paragraph, are withdrawn, except as restated below.

Claim Rejections - 35 USC § 112

Claims 32, 34, 37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of preventing chronic infection, does not reasonably provide enablement for full protection against a challenge infection (e.g., protection against acute infection). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. This is a modification of the previous enablement rejection. Example 15 clearly shows that the disclosed compositions are unable to prevent acute hepatitis. Therefore, it is maintained that claims 32 and 33 exceed the scope of the enabling disclosure.

Claim Rejections - 35 USC § 102

Claim Rejections - 35 USC § 103

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Claims 16, 17, 21-24, 26, 38-39 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Liang et al WO 98/21338, for reasons of record. Applicant argues that Liang discloses virus-like particles that do not only contain E1 but also contain Core, E2, P7 proteins, HCV RNA, and insect cell ER-derived membrane, and therefore does not anticipate the presently claimed invention. However, the claims do not exclude additional components, because they recite "comprising." Also, the specification contemplates as "specific oligomeric proteins": "all possible oligomeric forms of recombinantly expressed E1 and/or E2 envelope proteins which are not aggregates." The recombinantly-expressed virus-like particle reasonably appears to be an oligomeric form which is not an aggregate. Applicant further argues that Liang does not provide a working example for a prophylactic vaccine, "which the Examiner has argued is required with regard to the alleged lack of enablement of the present application." The instant claims are drawn to a composition, and the reference teaches a composition. Neither anticipation nor obviousness requires the prior art products to be demonstrated as effective for the same intended use, merely that the prior art teaches or adequately suggests a product encompassed by the claim.

Claims 16, 17, 20-28, 38-39 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Depla et al WO 99/67285 (in 3/16/2004 IDS). After reconsideration, the rejection of claims 29, 31-37 is withdrawn, since the reference does not teach or suggest (with reasonable expectation of success) a method of preventing evolution to a chronic infection or protecting

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against a challenge infection. However, claims 16, 17, 21-24, 26, 38-39 are drawn to compositions, and the reference teaches compositions which reasonably appear to have the same or similar components in the same or similar amounts as the instant claimed compositions. Furthermore, the reference teaches inducing an immune response in a mammal in Example 9, thereby meeting the limitations of claims 27-28. In regard to the alleged contradiction between the prior enablement rejection and the anticipation rejection, an applicant is required to meet both the "how-to-make" and "how to use" requirements of 35 USC 112, 1st paragraph, in order to obtain a patent; however, a product can be rendered unpatentable by prior art that does not teach or suggest any method of use whatsoever (In re Schoenwald, 964 F.2d 1122, 22 USPQ2d 1671 (Fed. Cir. 1992)).

Claims 16, 17, 21-28, 38-39 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over U.S. Patent No. 6,635,257, for essentially the same reasons as the rejection over its international equivalent Depla et al WO 99/67285. The comments with regard to a 132 declaration are part of the form paragraph provided by the PTO for use when a 102(e) rejection is made over a patent with a common applicant or assignee. The MPEP does not have a clear explanation of this boilerplate (at least, not one that is easily found). The examiner's best guess is that a 132 declaration can be used to show that the relevant parts of the patent disclosure derive from the instant inventive entity and not from the inventive entity of the patent (the patent inventors, of course, are required to be the inventors of all that is claimed, not necessarily the inventors of all that is disclosed).

Double Patenting

Claims 16, 17, 20-26, 38, 39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16, 19, 21 of U.S. Patent No. 6,635,257. As applicant did not argue this rejection, it is maintained.

Claims 16, 17, 20-26, 38-39 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15-26, 41-42 of copending Application No.09/995,860. As applicant did not argue this rejection, it is maintained.

Allowable Subject Matter

Claims 29, 31, 33, 35, 36 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

12/15/04

Mary Mosher
MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1600/400